

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
15 March 2001 (15.03.2001)

PCT

(10) International Publication Number  
**WO 01/17540 A1**

- (51) International Patent Classification<sup>7</sup>: **A61K 35/78**, 33/02, 33/36, 33/28, 33/38, A61P 35/02 (74) Agent: **BANERJEE, Sudipta**; L.S. Davar & Co., Monalisa, Flats 1B & 1C, 17 Camac Street, Calcutta 700 017 (IN).
- (21) International Application Number: **PCT/IN99/00042** (81) Designated State (*national*): **US**.
- (22) International Filing Date:  
7 September 1999 (07.09.1999) (84) Designated States (*regional*): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
- (25) Filing Language: **English**
- (26) Publication Language: **English** Published:  
— *With international search report.*
- (71) Applicant and  
(72) Inventor: **PRAKASH, Vaidya, Balendu** [IN/IN]; Mandir Marg, Turner Road, Clement Town, Dehradun 248 002 (IN).
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*



**WO 01/17540 A1**

(54) Title: **A PHARMACEUTICAL AYURVEDIC PREPARATION**

(57) Abstract: The present invention relates to a process on ayurvedic preparation comprising in the steps of subjecting silver, mercury, sulphur and arsenic trisulphide to the steps of detoxification, grinding the detoxified mercury and silver in the presence of a citrus juice and then adding detoxified sulphur and again subjecting to the step of grinding to obtain a greyish black powder, adding detoxified arsenic trisulphide thereto and subjecting to the step of grinding, imparting a shape such as a ball thereto, coating the ball with detoxified sulphur in the presence of a citrus juice and subjecting the coated ball to the step of slow firing, adding detoxified arsenic trisulphide and firing, repeating said steps of addition and firing ground in a citrus juice such that the weight of the ball is reduced by at least 10 % to obtain an intermediate, adding serpentine and delphinium root thereto.



WO 01/17540

PCT/IN99/00042

TITLE OF THE INVENTION

A PHARMACEUTICAL AYURVEDIC PREPARATION

FIELD OF INVENTION

5 This invention relates to a pharmaceutical ayurvedic preparation for the treatment of leukemia. The preparation of the present invention has a particular application for the treatment of acute myeloid leukemia, acute promyelocytic leukemia and acute lymphoblastic leukemia. The present invention also relates to a process for  
10 preparing the pharmaceutical ayurvedic preparation.

PRIOR ART

Chemical pharmaceutical preparations are normally prescribed for treatment of leukemia. No prior public literature is known for an ayurvedic preparation for  
15 treatment of leukemia.

OBJECTS OF THE INVENTION

An object of this invention is to propose a novel ayurvedic preparation for treatment of leukemia.  
Another object of this invention is to propose an ayurvedic  
20 preparation for treatment of leukemia and which does not have any side effects.

DESCRIPTION OF THE INVENTION

According to this invention, there is provided a process for the preparation of an ayurvedic preparation comprising  
25 in the steps of subjecting silver, mercury, sulphur and arsenic trisulphide to the steps of detoxification, grinding the detoxified mercury and silver in the presence of a citrus juice and then adding detoxified sulphur and again subjecting to the step of grinding to obtain a  
30 greyish black powder, adding detoxified arsenic trisulphide thereto and subjecting to the step of grinding,

imparting a shape such as a ball thereto, coating the ball with detoxified sulphur in the presence of a citrus juice and subjecting the coated ball to the step of slow firing, adding detoxified arsenic trisulphide and firing, repeating said steps of addition and firing ground in a citrus juice such that the weight of the ball is reduced by at least 10% to obtain an intermediate, adding serpentine and delphenium root thereto.

The expression detoxification used herein is not intended to imply that silver, mercury, sulphur and arsenic trisulphide are treated such as to detoxify the elements in the mixture stage, but to imply that such elements do not exhibit any adverse side effects in the end preparations.

In accordance with this invention, silver in a purified form which is subjected to a step of detoxification. Such a step of detoxification consists in converting silver bars into sheets and then to repetitive steps of heating and introduction into sesame oil. By way of example and without implying any limitation, such a step of heating and introducing into sesame oil is repeated several times, such as seven times.

Thereafter, the treated silver is again heated and then introduced into butter milk. The step of heating and introduction into butter milk after each step of heating is also repeated several times, such as seven times.

The partially detoxified silver is again heated and then introduced into cow urine and which step is repeated several times, such as seven times.

The treated silver is again heated and introduced into a herbal composition. Such a step of heating and introduction into a herbal composition is again preferably repeated several times, such as seven times. The herbal composition comprises amla, harar and behera and present preferably in equal parts.

he  
is  
ow  
l,  
n  
d  
g  
i  
:  
The treated silver is again heated several times and then after each step of heating is treated with kutli. Such a step is also repeated several times, such as seven times. The aforesaid step consists in the detoxification of silver.  
5 The process of the present invention includes the step of detoxification of mercury. For this purpose, an amalgam is first prepared from a mixture of copper, which may be in the form of wire, in lemon juice and mercury. Preferably  $1/2$ - $1/8$  parts of copper wire is added to every  
10 one part of mercury which is then ground to obtain an amalgam. Such an amalgam is then subjected to a step of distillation to extract mercury therefrom. The step of grinding and distillation is effected several times in order to obtain detoxified mercury. Preferably but without  
15 implying any limitation to the step of detoxification is carried seven times.

The next step is the process consists in the purification of sulphur. For this purpose, crystalline sulphur is introduced into a crucible and having melted butter  
20 therein. Preferably, equal amounts of melted butter and sulphur are introduced into the crucible and heated on a low fire. Trifla is then added to the mixture and whereby a scum of pure sulphur is formed and removed.

The process also comprises in introducing arsenic trisulphide disposed within a cotton cloth and introduced  
25 into a vessel containing calcium oxide solution and then into another vessel of pumpkin juice or vice versa. The arsenic trisulphide is heated in calcium oxide solution and pumpkin juice for a period of 3 to 5 hours, such as  
30 4 hours and, then dried.

The next step in the process consists in grinding detoxicated silver and mercury in the presence of citrus juice, such as lemon juice, and such that detoxicated silver is dissolved in mercury. Preferably, one part of  
35 detoxicated silver is added to one part of mercury and

ground in the presence of lemon juice to form a powder. Thereafter, purified sulphur is added thereto and ground to greyish black powder. Preferably, one part of purified sulphur is added thereto. Upon grinding and obtaining a greyish black powder purified arsenic trisulphide is added to the greyish black powder in the presence of a citrus juice, such as lemon juice, which is then subjected to a step of grinding to obtain a paste. Such a paste is shaped into balls and then air dried. Preferably, one part of arsenic disulphide is added thereto.

The next step in the process consists in coating such balls with a paste of sulphur in lemon juice.

Such a ball is introduced into an earthenware vessel which is sealed with a strip of cotton and dipped in clay. The vessel is introduced into a bed containing dry cowdung which is then fired such that the temperature rises to a temperature of 500-600°C and then gradually reduces.

The vessel is then opened and arsenic trisulphide is added thereto in the presence of lemon juice and subjected to the step of firing. The step of adding arsenic trisulphide and firing is repeated 30-60 time to obtain a more potent intermediate product, and such that the weight is reduced by at least 10%.

Such an intermediate product is thereafter added to serpentine and delphenium root and ground in distilled rose water for approximately seven days repeated with sandalwood water for seven day and finally with latakasturi water for seven days to obtain a paste which is then shaped into balls.

Further objects and advantages of this invention will be more apparent from the ensuing example and clinical trials.

#### EXMAPLE

Silver, mercury, sulphur and arsenic trisulphide was

detoxified in a manner as described hereinabove. Thereafter, the ball was prepared consisting of:

detoxified silver = 250 gms

detoxified mercury = 250 gms

5 detoxified sulphur = 500 gms

detoxified arsenic

trifulphide= 250 gms

The ball had a weight of 1250 gms and then provided with a coating of detoxified sulphur ground in lemon juice and such that the coated ball had a weight of 1400 gms. Such a ball was then introduced into an earthen vessel or pot and sealed with a strip of cotton, dipped in clay. The vessel is introduced into a pit containing cow dung and fired. Such a process was repeated as shown in Table 1 to produce the intermediate product. Thereafter, the final product was prepared in a manner as described herein above.

T A B L E 1

	VESSEL	GROUND WITH	PERIOD	WT. BEFORE	PERIOD	WT.	
20	ARSENIC	LEMON	DAYS	FIRING gm	OF	AFTER	
	trisul-	Juice			FIRING	FIRING	
	phide				days	gm	
	1	0	0	1400	1	940	
	1	25g	450ml	6	1120	1	975
25	1	25g	400ml	17	1100	1	940
	1	25g	400ml	22	1050	1	940
	2	25g	400ml	29	1110	1	930
	2	25g	450ml	36	1090	1	975
	2	25g	400ml	41	1070	1	940
30	2	25g	400ml	50	1040	1	940
	2	25g	450ml	58	1050	1	930
	2	25g	550ml	67	1080	1	940

	2	25g	500ml	73	1070	1	950
	2	25g	750ml	80	1070	1	970
	2	25g	750ml	84	1050	1	970
	2	25g	800ml	89	1060	1	940
5	2	25g	900ml	96	1080	1	950
	2	25g	900ml	103	1100	1	1000
	2	25g	900ml	110	1120	1	970
	2	25g	900ml	116	1050	1	950
	2	25g	900ml	121	1020	1	950
10	2	25g	750ml	128	1050	1	990
	2	25g	800ml	135	1080	1	980
	2	25g	750ml	140	1050	1	950
	2	25g	650ml	148	1050	1	950
	2	25g	700ml	153	1020	1	950
15	2	25g	700ml	159	1080	1	980
	2	25g	650ml	173	980	1	920

The results of clinical trials on patients with the preparation of the present invention were as follows:

T A B L E 2

DETAILS OF THE PATIENTS WHO COMPLETED  
90 DAYS OF TREATMENT FOR ACUTE  
PROMYELOCYTIC LEUKEMIA WITH PRESENT  
MEDICINE

S.No.	Name/Age	Category	<u>Duration of Treatment</u>		Status after
		<u>Fresh/</u> <u>Relapse</u>	From	To	90 days
1.	ARK/41	F	09.09.1997	30.01.1998	Complete remission on 26.12.1997
2.	VR/40	F	04.12.1997	22.04.1999	Complete remission on 14.03.1998
3.	PK/50	F	04.12.1997	20.03.1998	Complete remission



					or 16.03.1998
4.	VC/48	R	22.12.1997	15.04.1998	Complete remission on 01.04.1998
5.	F/29	R	09.04.1998	07.12.1998	Bone marrow not done, blood report normal
6.	NS/15	R	18.04.1998	30.01.1999	Complete remission on 25.07.1998
7.	PR/48	F	26.01.1999	15.05.1999	Complete remission on 12.04.1999
5	8.	MS/28	R	19.02.1999	15.06.1999 Complete remission on 11.06.1999
9.	PS/29	R	25.03.1999	05.07.1999	Complete remission on 03.07.1999
10.	MN/30	R	30.03.1999	10.07.1999	Complete remission on 05.07.1997

F-Fresh, R-Relapse

T A B L E 3

10 DETAILS OF BONE MARROW OF THE PATIENTS WHO  
COMPLETED 90 DAYS OF TREATMENT FOR ACUTE  
PROMYELOCYTIC LEUKEMIA

S.No.	Name/Age	Before Ayurvedic treatment	After 90 days of Ayurvedic treat- ment
1.	ARK/41	BM no.5239863, replaced with abnormal promyelocytes-M3	PS and BM no. 523986-D, is free of evidence of M3, normal hemopoietic cell
15	2. VR/40	Bone marrow shows abnormal promyelocytes-M3	Bone marrow in remission, no

			promyelocytic cells seen.
3.	PK/50	Bone marrow replaced with abnormal promyelocytes-M3	Bone marrow in remission with normal cells
4.	VC/48	Bone marrow shows hyper granulated M3 cells	Bone marrow in remission with normal hemopoitic cells
5.	F/29	Bone marrow shows abnormal promyelocytes-M3	Bone marrow not done
6.	NS/15	Bone marrow shows 60-65% abnormal promyelocytes, APL relapse, N <sub>8-10</sub> , L <sub>3-5</sub> , MRBC 25%	Bone marrow in remission, no APL cells identi- fied, PS shows P <sub>64</sub> L <sub>33</sub> E <sub>2</sub> M <sub>1</sub>
7.	PR/48	Bone marrow shows hyper granulated promyelocytes AML-M3	Bone marrow shows normal hemopoitic with mild megalo- blastic change. There is no morphological evidence of residual leukemia
8.	MS/28	Bone marrow in relapse- AML-M3	Bone marrow shows normal hemopoitic. No leukemic cells identified
9.	PS/29	Bone marrow shows total replacement by abnormal hyper granular promyelocytes	Bone marrow shows normal hemopoitic cells of all series. No evidence of leuk- emia seen
10.	MN/30	Bone marrow shows abnormal	Bone marrow shows

promyelocytes along with  
few normal neutrophils-  
AML-M3 relapse

normal hemopoietic  
cells in all  
series. No  
evidence of  
residual leukemia

T A B L E  
DETAILS OF BLOOD REPORT OF TREATED APML CASES

S. No.	Name/Age	Blood report	First day	After 30 days	After 60 days	After 90 days
1.	ARK/41	Hb gm%	7.1	9.9	13.5	14.8
		TLC	1100	1450	5100	3100
		DLC	N <sub>10</sub> L <sub>30</sub> Abn <sub>60</sub>	N <sub>31</sub> L <sub>69</sub>	N <sub>60</sub> L <sub>34</sub> E <sub>6</sub>	N <sub>57</sub> L <sub>27</sub> E <sub>10</sub> M <sub>4</sub>
		ESR	138	37	8	-
		Platelets	19000	258000	172000	174000
2.	VR/40	Hb gm %	5.6	8.2	9.6	10.0
		TLC	1600	620	3200	3900
		DLC	N <sub>35</sub> L <sub>29</sub> E <sub>2</sub> M <sub>2</sub> Abn <sub>30</sub>	N <sub>32</sub> L <sub>22</sub> E <sub>4</sub> M <sub>2</sub> Abn <sub>20</sub>	N <sub>40</sub> L <sub>38</sub> E <sub>4</sub> Abn <sub>18</sub>	N <sub>73</sub> L <sub>21</sub> E <sub>4</sub> M <sub>2</sub>
		ESR	-	-	-	-
		Platelets	40000	180000	200000	200000
3.	PK/50	Hb gm %	10.2	9.3	10.1	13.9
		TLC	2000	6800	7000	9000
		DLC	N <sub>7</sub> L <sub>10</sub> M <sub>2</sub> Abn <sub>81</sub>	N <sub>70</sub> L <sub>30</sub>	N <sub>66</sub> L <sub>33</sub> E <sub>1</sub>	N <sub>63</sub> L <sub>37</sub>
		ESR	-	-	10	-
		Platelets	35000	25000	252000	330000
4.	VC/48	Hb gm %	8.0	9.5	11.8	9.6
		TLC	28000	650	7500	4800
		DLC	N <sub>30</sub> L <sub>35</sub> E <sub>5</sub> M <sub>4</sub> Abn <sub>26</sub>	N <sub>20</sub> L <sub>80</sub>	N <sub>58</sub> L <sub>26</sub> M <sub>2</sub> Abn <sub>4</sub>	N <sub>79</sub> L <sub>13</sub> Abn <sub>4</sub>
		ESR	75	-	-	-
		Platelets	110000	22000	85000	120000
5.	F/29	Hb gm %	9.0	9.0	5.0	9.6

		TLC	4900	4900	2500	1000
		DLC	N <sub>8</sub> L <sub>47</sub> M <sub>5</sub> Abr <sub>40</sub>	N <sub>8</sub> L <sub>45</sub> M <sub>5</sub> Abr <sub>40</sub>	N <sub>45</sub> L <sub>54</sub> B <sub>1</sub>	N <sub>26</sub> L <sub>5</sub> E <sub>1</sub> Abr <sub>46</sub>
		ESR	-	-	90	130
		Platelets	75000	75000	18000	55000
6.	NS/15	Hb gm %	12.9	8.4	11.0	11.7
		TLC	400	63200	7900	8500
		DLC	N <sub>64</sub> L <sub>36</sub>	N <sub>5</sub> L <sub>10</sub> Abr <sub>85</sub>	N <sub>57</sub> L <sub>40</sub> E <sub>3</sub>	N <sub>60</sub> L <sub>37</sub> E <sub>3</sub>
		ESR	-	42	5	5
		Platelets	130000	64000	238000	218000
7.	PR/48	Hb gm %	12.7	10.2	10.5	11.4
		TLC	2000	3000	3500	5500
		DLC	N <sub>7</sub> L <sub>43</sub> Abr <sub>50</sub>	N <sub>13</sub> L <sub>27</sub> E <sub>4</sub> Abr <sub>56</sub>	N <sub>48</sub> L <sub>37</sub> E <sub>6</sub> Abr <sub>2</sub> B <sub>1</sub>	N <sub>55</sub> L <sub>41</sub> B <sub>1</sub> Abr <sub>2</sub>
		ESR	43	-	-	-
		Platelets	76000	90000	298000	310000
8.	MS/28	Hb gm %	7.0	10.5	13.0	14.3
		TLC	12200	5700	7200	9200
		DLC	N <sub>8</sub> L <sub>30</sub> Abr <sub>62</sub>	N <sub>55</sub> L <sub>44</sub> E <sub>1</sub> M <sub>2</sub>	N <sub>73</sub> L <sub>22</sub> E <sub>5</sub>	N <sub>64</sub> L <sub>33</sub> E <sub>3</sub>
		ESR	48	5	-	-
		Platelets	36000	103000	141000	169000
9.	PS/29	Hb gm %	8.4	12.2	15.0	14.9
		TLC	2240	2900	5200	4600
		DLC	N <sub>5</sub> L <sub>10</sub> M <sub>5</sub> Abr <sub>70</sub>	N <sub>33</sub> L <sub>4</sub> L <sub>50</sub> E <sub>24</sub> 4 <sup>M</sup> <sub>13</sub> 4 <sup>B</sup> <sub>0</sub> 3	N <sub>46</sub> 9 <sup>L</sup> <sub>33</sub> 2 <sup>E</sup> <sub>8</sub> 3 <sup>M</sup> <sub>11</sub> 2 <sup>B</sup> <sub>0</sub> 4	N <sub>48</sub> 7 <sup>L</sup> <sub>30</sub> 5 <sup>E</sup> <sub>8</sub> 6 <sup>M</sup> <sub>12</sub> 1 <sup>B</sup> <sub>0</sub>
		ESR	-	-	5	7
		Platelets	25000	298000	202000	189000
10.	MN/30	Hb gm %	6.5	9.0		9.8
		TLC	8200	7300		5600
		DLC	N <sub>27</sub> L <sub>48</sub> E <sub>1</sub> Abr <sub>24</sub>	N <sub>71</sub> L <sub>23</sub> M <sub>6</sub>		N <sub>82</sub> L <sub>17</sub> M <sub>1</sub>
		ESR	-	-		60
		Platelets	120000	230000		150000

N-Neutrophils, L-Lymphocyte, E-Eosinophils, M-Monocyte, B-Basophil;  
Abr-Abnormal cell

DETAILS OF LIVER, KIDNEY FUNCTION AND LIPID PROFILE OF THE PATIENTS  
TREATED FOR ACUTE PROMYELOCYTIC LEUKEMIA

S.no.	Name/Age	Pre Ayurvedic treatment			After 90 days of Ayurvedic treatment		
		LFT	Lipid profile	KFT	LFT	Lipid profile	KFT
1.	ARK/41	NA	NA	NA	Bilirubin (T)-1.2 mg/dl Bilirubin(D)-0.3 mg/dl Protein total -7.8 mg/dl SGOT-29, SGPT-35 Alk.P.-161	NA	Blood -23 mgs/dl Serum-0.8 mg/dl creat-inine
2.	VR/40	NA	NA	NA	NA	NA	NA
3.	PK/50	Bilirubin(T)-0.4 mgs/100ml Bilirubin(C)-0.2 mgs/100ml SGOT-75u/l, SGPT-35 Alk.P.-324 u/l	NA	Blood urea NA -21mgs/100 Serum creatinine -1.1 mgs/100ml	NA	NA	Blood -34mgs % serum creat-inine-1.3mgs %
4.	VC/48	Bilirubin(T)-0.7 mgs Bilirubin(C)-0.3 mgs Protein total-7.0 gm% Albumin-3.9gm% Globulin-3.1gm% SGOT-20u/l, SGPT-25 Alk.P.-138	Total cholesterol-168 mg/dl HDL cholesterol-380 mg/dl VLDL cholesterol-29 mg/dl LDL cholesterol-101 mg/dl Triglycerides-433 mg/dl	Blood urea -26 mg% Serum creatinine -1.0 mg% Serum uric acid-4.9 mg%	Bilirubin(T)-0.72 mg/dl Bilirubin(D)-0.3 mg/dl Protein total -6.2 mg/dl Albumin-3.6 SGOT-20u/l, SGPT-25 Alk.P.-430	Cholestrol-198 mg/dl	NA

5.	F/29	NA	NA	NA	NA	NA	NA
6.	NS/15	Bilirubin(T)-0.5 mg/dl Bilirubin(D)-0.3 mg/dl Protein total- 7.1 g/dl Albumin-3.4 g/dl SGOT-10u/l, SGPT-12 Alk.P.-103	Total cholesterol- 185 mg% HDL cholesterol- 42 mg% VLDL cholesterol- 21 mg% LDL cholesterol- 122 mg% Triglycerides- 105 mg%	Blood sugar -90 mg% Blood urea -19 mg% Serum creatinine -0.8 mg%	NA	NA	NA
7.	PR/48	Bilirubin(T)-1.57 mg/dl Bilirubin(D)-0.14 mg/dl Bilirubin(ID)-1.43 mg/dl Protein total-6.9 mg/dl SGOT-29, SGPT-22 Alk.P.-183.8	NA	Blood-34 mgs/dl urea Serum-1.2mg/dl creatinine Uric-2.8mg/dl acid	Bilirubin(T)- 0.6mg% Bilirubin(D)- 0.6 mg% Bilirubin(ID)- 0.5 mg% Protein total- 6.4 mg% Albumin-3.7 mg% SGOT-49u/l, SGPT-38u/l, GGPT-17u/l Alk.P.-17 u/l	Total choles- trol-198 mg/dl HDL cholesterol -49 mg% LDL cholesterol -150 mg% VLDL cholest- rol-27 mg% Triglycerides -136 mg% Phosphorus- 4.3 mg% Sodium-114 meg/l Chloride- 107 meg/l	Blood urea -33 mg/dl Serum creatinine -0.5 mg/dl
8.	MS/28	NA	NA	NA	NA	Total chol- estrol-146 mg/dl HDL cholest- rol-32 mg/ dl LDL cholest- rol-53 mg/ dl Triglycer- ides-306 mg/dl	Blood urea -33 mg/dl Serum creatinine -0.5 mg/dl

9.	PS/29	<p>Bilirubin(T)- 0.4 mg/dl Bilirubin(D)- -0.2 mg/dl Bilirubin(ID)- 0.2 mg/dl Protein total- 7.6 g/dl Albumin-4.4 g/dl SGOT-126 u/l, SGPT-49 u/l GGTP-38 u/l Alk.P.-217 u/l</p> <p>Total cholest- rol-205 mg/dl HDL cholestrol- 31.25 mg/dl VLDL cholestrol- 26.99% LDL cholestrol- 118.42 mg/dl Triglycerides- 433 mg/dl</p> <p>Blood urea -45 mg/dl Serum creat- inine-0.90 mg/dl Calcium- 10.1 mg/dl Phosphorus- 4.1 mg/dl Sodium-147 mEq/l Chloride- 103 mEq/l Potassium- 4.20 mEq/l</p>	<p>Bilirubin(T)- -0.7 mg/dl Bilirubin(D)- 0.2 mg/dl Bilirubin(ID)- 0.5 mg/dl Protein total- 7.7 g/dl Albumin-4.6 g/dl SGOT-253 u/l, SGPT-365 u/l GGTP-89 u/l Alk.P.-473 u/l</p> <p>Total cholest- rol-156 mg/dl HDL cholest- rol-22.15 mg/dl LDL cholest- rol-94.09 mg/dl VLDL cholest- rol-27.35 mg/dl Trigly- cerides-187 mg/dl</p> <p>Blood urea -17 mg/dl Serum creat- inine-1.0 mg/d Calcium-9.7 mg/dl Phosphorus- 2.9 mg/dl Sodium-150 mE mEq/l Chloride-105 mEq/l Potassium- 4.90 mEq/l</p>	<p>Total cholest- rol-185 mg/dl HDL cholest- rol-26mg/dl VLDL cholest- rol-93 mg/dl LDL cholest- rol 106 mg/dl Triglycerides- 506 mg/dl</p> <p>Blood urea 46 mg/dl Serum creat- inine-1.05 mg/dl Calcium- 8.25 mg/dl</p> <p>Bilirubin(T)- 0.7 mg/dl Bilirubin(D)- 0.3 mg/dl SGOT-22.8iu/l SGPT-27.6iu/l Alk.P.-360.5 iu/l</p> <p>Total cholest- rol-136.8 mg/dl HDL cholest- rol-46.2 mg/dl LDL cholest- rol-56.5 mg/dl VLDL cholest- rol-34.1 mg/dl</p> <p>Serum urea-29.3 mg/dl Serum creatinine -1.0 mg/dl Serum creatinine -46.2 mg/dl LDL cholest- rol-56.5 mg/dl VLDL cholest- rol-34.1 mg/dl</p>
10.	MN/30	<p>Bilirubin(T)- 1.7 mg/dl Bilirubin(D)- 1.13 mg/dl Bilirubin(ID)- 0.57 mg/dl SGOT-28 u/l, SGPT-35 u/l, Alk.P.-229 u/l</p>	<p>Bilirubin(T)- 0.7 mg/dl Bilirubin(D)- 0.3 mg/dl SGOT-22.8iu/l SGPT-27.6iu/l Alk.P.-360.5 iu/l</p>	<p>Total cholest- rol-185 mg/dl HDL cholest- rol-26mg/dl VLDL cholest- rol-93 mg/dl LDL cholest- rol 106 mg/dl Triglycerides- 506 mg/dl</p> <p>Blood urea 46 mg/dl Serum creat- inine-1.05 mg/dl Calcium- 8.25 mg/dl</p> <p>Bilirubin(T)- 0.7 mg/dl Bilirubin(D)- 0.3 mg/dl SGOT-22.8iu/l SGPT-27.6iu/l Alk.P.-360.5 iu/l</p> <p>Total cholest- rol-136.8 mg/dl HDL cholest- rol-46.2 mg/dl LDL cholest- rol-56.5 mg/dl VLDL cholest- rol-34.1 mg/dl</p> <p>Serum urea-29.3 mg/dl Serum creatinine -1.0 mg/dl Serum creatinine -46.2 mg/dl LDL cholest- rol-56.5 mg/dl VLDL cholest- rol-34.1 mg/dl</p>

## I CLAIM:

1. A process or ayurvedic preparation comprising in the steps of subjecting silver, mercury, sulphur and arsenic trisulphide to the steps of detoxification, grinding the  
5 detoxified mercury and silver in the presence of a citrus juice and then adding detoxified sulphur and again  
subjecting to the step of grinding to obtain a greyish black powder, adding detoxified arsenic trisulphide thereto  
and subjecting to the step of grinding, imparting a shape  
10 such as a ball thereto, coating the ball with detoxified sulphur in the presence of a citrus juice and subjecting  
the coated ball to the step of slow firing, adding  
detoxified arsenic trisulphide and firing, repeating  
said steps of addition and firing ground in a citrus juice  
15 such that the weight of the ball is reduced by at least  
10% to obtain an intermediate, adding serpentine and  
delphenium root thereto.

2. A process as claimed in claim 1 wherein the coated  
balls are introduced into an earthen vessel, sealed and  
20 then fired in the presence of cow dung.

3. A process as claimed in claim 1 wherein silver is  
detoxified by heating silver sheets to a red hot state,  
and then introducing into sesame oil, subjecting the sheets  
to repeated steps of heating and treatment with sesame  
25 oil.

4. A process as claimed in claim 3 wherein the sesame  
treated silver is subjected to repetitive steps of heating  
and then treating with butter milk.

5. A process as claimed in claim 4 wherein the butter  
milk treated silver is subjected to repetitive steps of  
30 heating and then treating with cow urine.

6. A process as claimed in claim 5 wherein the cow urine  
treated silver is then subjected to repetitive steps of  
heating and treatment in a herbal composition comprising  
35 amla, harar and bahera.



7. A process as claimed in claim 1 wherein the herbal treated silver is subjected to repetitive steps of heating and treatment with kulthi.

8. A process as claimed in claim 1 wherein the citrus juice is lemon juice.

9. A process as claimed in claims 3 to 7 wherein said repetitive steps comprise 7 repetitive steps.

10. A process as claimed in claim 1 wherein the step of detoxification of mercury comprises in preparing an amalgam of copper, mercury and a citrus juice, subjecting such an amalgam to repeated steps of distillation to obtain detoxified mercury.

11. A process as claimed in claim 1 wherein the step of detoxification of sulphur comprises in heating crystalline sulphur in the presence of melted butter, and then introducing into triffla to obtain a scum of pure sulphur which is then removed therefrom.

12. A process as claimed in claim 1 wherein the step of detoxification of arsenic trisulphide comprises in wrapping arsenic trisulphide in cotton cloth and then introduced in a vessel of calcium oxide solution and into another vessel of pumpkin juice and boiled each time for a period of 3 to 5 hours.

13. A process as claimed in claim 1 wherein one part of detoxified silver is ground with one part of detoxified mercury in a citrus juice and that one part of detoxified sulphur is then added thereto obtain a greyish black powder.

14. A process as claimed in claim 12 wherein one part of arsenic trisulphide ground in a citrus juice is added to the greyish black powder and made into a shape.

15. A process as claimed in claim 14 wherein one part of detoxified sulphur is ground in citrus juice and coated to said shape and then introduced in said vessel and tired in cowdung.

16. A process as claimed in claim 1 wherein vessel containing said fired mixture is opened and further arsenic trisulphide ground in the presence of lemon juice is added, the vessel closed and again fired and subjected to repeated  
5 steps to obtain a potent preparation.

17. A process as claimed in claim 16 wherein one part of the potent preparation is added to one part of serpentine and one part of delphenium root and ground in distilled rose water followed sandal wood water and  
10 to latakasturi water.

18. A process for producing an ayurvedic preparation for the treatment of leukemia substantially as herein described.

# PATENT COOPERATION TREATY

# PCT

REC'D 27 SEP 2001

PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference <b>IN/PA-210</b>	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. <b>PCT/IN99/00042</b>	International filing date (day/month/year) <b>07/09/1999</b>	Priority date (day/month/year) <b>07/09/1999</b>
International Patent Classification (IPC) or national classification and IPC <b>A61K35/78</b>		
Applicant <b>PRAKASH, Vaidya, Balendu</b>		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
  - ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand  <b>29/03/2001</b>	Date of completion of this report  <b>25.09.2001</b>
Name and mailing address of the international preliminary examining authority:  <b>European Patent Office</b> <b>D-80298 Munich</b> <b>Tel. +49 89 2399 - 0 Tx: 523656 epmu d</b> <b>Fax: +49 89 2399 - 4465</b>	Authorized officer  <b>Ludwig, G</b>  Telephone No. +49 89 2399 8698 <div style="text-align: right;">  </div>



# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IN99/00042

## I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, pages:**

1-13 as originally filed

**Claims, No.:**

2-14,16,17 as originally filed

1,15,18 as received on 11/09/2001 with letter of 24/08/2001

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/IN99/00042

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes:	Claims	1-18
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-18
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-18
	No:	Claims	

2. Citations and explanations  
**see separate sheet**

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:  
**see separate sheet**





**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

---

International application No. PCT/IN99/00042

Item V:

1. There appears to be no relevant prior art.

The process of preparing/use of an ayurvedic preparation as described in claims 1-18 appears therefore to be novel and inventive.

According to the data presented in the application said preparation can be used successfully for the treatment of leukemia.

Item VIII:

2. In claim 1 (line 2) the word "in" should be deleted for the sake of clarity.
3. The word "fried" in claim 15 does not appear to be originally disclosed.

Only the word "fired" appears to be disclosed originally (cf. claim 2).



24/08/2001 19:00 91-33-2406

**FACSIMILE TRANSMISSION**

Telephones : + 91-33-247-3996  
 + 91-33-247-5918  
 + 91-33-280-5536

Telefax : + 91-33-247-5886  
 + 91-33-240-6292  
 + 91-11-646-4443

E-Mail : davar@cal2.vsnl.net.in  
 lsdavar@cal2.vsnl.net.in

Web Site : <http://www.lsdavar.org.in>

Dr (Mrs) S. Banerjee

From

European Patent Office (IPEA),

To

G Ludwig Esq.

Attn

Examiner

No. of Pages

(including this page)

From

**L. S. DAVAR & CO.**

Patent and Trade Mark Attorneys

Flats 1B & 1C, "MONALISA"

17, Camac Street

Calcutta- 700 017

INDIA

24.8.2001

Date

4989 2399-4465

Facsimile No.

ONE + ONE

Dear Sir,

Re: Patent Application No. PCT/IN99/00042 of 7.9.99  
 of Prakash Vaidya Balendu

Kindly refer to the international preliminary examination report dated 27.7.2001 issued in respect of the instant patent application of which we are to submit as follows:

Regarding the objections, we suggest to amend claims 1, 15 and 19 to read as follows:

Claim 1: "A process for preparing an ayurvedic preparation comprising in the steps of subjecting silver, mercury, sulphur and arsenic trisulphide to the steps of detoxification, grinding the detoxified mercury and silver in the presence of a citrus juice and then adding detoxified sulphur and again subjecting to the step of grinding to obtain a greyish black powder, adding detoxified arsenic trisulphide thereto and subjecting to the step of grinding, imparting a shape such as a ball thereto, coating the ball with detoxified sulphur in the presence of a citrus juice and subjecting the coated ball to the step of slow firing, adding detoxified arsenic trisulphide and firing, repeating said steps of addition and firing ground in a citrus juice such that the weight of the ball is reduced by at least 10% to obtain an intermediate, adding serpentine and delphinium root thereto".

Contd...p2/-

24-08-2001

Empfangszeit 24. Aug. 15:29



Printed 14-09-2001

408REPLY

99961271-IN9900042

24/08/2001 19:00 91-37-2486292

L S DAVAR & CO

Claim 15: "A process as claimed in claim 14 wherein one part of detoxified sulphur is ground in citrus juice and coated to said shape and then introduced in said vessel and fried in cowdung".

Claim 18: "A process for preparing an ayurvedic preparation for the treatment of leukemia as claimed in claims 1 to 17".

Please let us know if the above mentioned amendments meets your requirements.

Yours sincerely,

*S Banerjee*

(S Banerjee)

SB/am

Empfangszeit 24. Aug. 15:29

24-08-2001

